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PATENT



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SPINAL FIXATION APPARATUS AND METHOD

Background

Field of the Invention

This invention relates to medical instrumentation for achieving spinal fusion and, more particularly, to a novel, highly adaptive, and interchangeable component system and method for fixation of the lumbar spine and lumbosacral spine to aid the fusion of these spinal regions.

Related Applications

This application is a continuation-in-part application of my copending application Serial Number 08/232,371, filed 25 April 1994 for SPINAL FIXATION APPARATUS AND METHOD now U.S. Patent No. 5,498,262 issued 12 March 1996 which was a continuation-in-part application of Serial Number 07/999,005 filed 31 December 1992 for LUMBAR SPINE FIXATION APPARATUS AND METHOD now U.S. Patent No. 5,306,275 issued 26 April 1994.

The Prior Art

The spine is a flexible, multi-segmented column that supports the upright posture in a human while providing mobility to the axial skeleton. The lumbar spine serves the functions of encasing and protecting vital neural elements and provides structural support for the body by transmitting the weight of the body through

2

1 the pelvis to the lower extremities. Since there are no ribs  
2 attached to the lumbar spine, it has a relatively wide range of  
3 motion.

4 The spine is made up of bone, intervertebral discs, synovial  
5 joints with their articular cartilage, synovial capsules and, as  
6 part of the back, is surrounded by supporting ligaments, muscle,  
7 fascia, blood vessels, nerves, and skin. As in other areas of the  
8 body, these elements are subject to a variety of pathological  
9 disturbances: inflammation, trauma, neoplasm, congenital  
10 anomalies, disease, etc. In fulfilling its role in the back, the  
11 spine can be subjected to significant trauma which is assumed to  
12 play a dominant role in the etiology of low back pain. Trauma  
13 frequently results in damage at the upper end of the lumbar spine,  
14 where the mobile lumbar segments join the less mobile dorsal spine.  
15 Excessive forces on the spine can not only produce life-threatening  
16 traumatic injuries, but may contribute to an increased rate of  
17 degenerative change. Degenerative changes tend to develop in the  
18 lower lumbar intervertebral discs, most commonly in the third  
19 decade. Osteoarthritis produces changes in the facet joints by  
20 middle age.

21 Certain severe cases of spine anomalies, such as a congenital  
22 scoliotic spine, or scoliosis developed as the result of diseases  
23 as cerebral palsy or muscular dystrophy, require surgery and  
24 instrumentation to correct or at least lessen the anomalous spine  
25 curvature. If exterior brace treatment has failed or a large  
26 progressive curve has developed without treatment, surgery can be

1 used to diminish the curve. Severe scoliosis that goes untreated  
2 can cause deformities of the ribs that restrict the lung and later  
3 cause serious breathing problems, heart disease, or severe back  
4 pain.

5 One of the methods used to treat disabling pain, neurological  
6 compromise, or deformity produced by any of the above noted  
7 pathological conditions is fusion. The earliest spinal fusion  
8 techniques were basically posterior interlaminar fusions.  
9 Subsequently, later techniques led to the evolution of  
10 posterolateral techniques that allow a larger area for bone  
11 grafting and fusion. The relatively high rate of unsatisfactory  
12 results with traditional fusion techniques led to the evolution of  
13 lumbosacral fusion involving the use of hardware or instrumentation  
14 in an attempt to achieve stability and thus fusion or correction of  
15 deformity and stability followed by fusion. Internal spinal  
16 fixation increases rigidity and results in a high rate of fusion.  
17 This increased fusion rate and decreased pseudarthrosis rate gives  
18 better results and can significantly reduce postoperative pain and  
19 time for convalescence. Spinal fixation using instrumentation also  
20 allows correction of deformities and maintenance of that correction  
21 during consolidation by fusion. The primary considerations of the  
22 indications for spinal instrumentation are the magnitude of  
23 instability, the plane of deformity, and the available intact  
24 anatomy.

25 The past decade or two has seen an extensive development of  
26 internal devices for the lumbar and lumbosacral spine fixation.

1 The following patents are typical of the patents in this field:  
2 Edwards (U.S. Patent No. 4,569,338) teaches a sacral fixation screw  
3 having an aperture in the top for the engagement of a hook.  
4 Steffee (U.S. Patent No. 4,648,388) teaches an apparatus for  
5 imposing a force on the spinal column. Howland et al. (U.S. Patent  
6 No. 4,653,481) teach a spine fixation system having a plurality of  
7 screw clamp assemblies inserted through the pedicle and vertebral  
8 body and affixed to a rigid rod. Steffee (U.S. Patent No.  
9 4,719,905) teaches an apparatus including a rod, a plurality of  
10 clamps, and a plurality of fastener assemblies for securing the rod  
11 to a spinal column. Puno et al. (U.S. Patent No. 4,805,602) teach  
12 an apparatus for the internal fixation of the spine, the apparatus  
13 including two sets of implants each consisting of a rod and a  
14 plurality of vertebral anchors. Heinig et al. (U.S. Patent No.  
15 4,887,595) teach a plate and screw system for maintaining the  
16 relative position of the spinal bodies of a spinal column. Sherman  
17 (U.S. Patent No. 4,887,596) teaches a pedicle screw for use in  
18 internal fixation of the spine. Gotzen et al. (U.S. Patent No.  
19 4,944,743) teach an implantable fixation device having a support  
20 bar with jaw supports threadedly engaged to the support bar.  
21 Gaines, Jr. (U.S. Patent No. 4,950,269) teaches a rod and fastener  
22 apparatus for connecting the rod to the vertebra of a spinal  
23 column. Krag et al. (U.S. Patent No. 4,987,892) teach a pedicle  
24 screw and rod apparatus for spinal fixation. Cotrel (U.S. Patent  
25 No. 5,005,562) teaches an implant for spinal fixation, the implant  
26 including a rod and pedicle screws and hooks mountable to the rod.

1     Howland (U.S. Patent No. 5,030,220) teaches an implantable spinal  
2     fixation system that uses a pedicle screw to secure the  
3     longitudinal rods to the spine. An improved locking system  
4     maintains the structural integrity of the construct. Cozad et al.  
5     (U.S. Patent No. 5,074,864) teaches a mid-line clamp assembly for  
6     use in posterior spinal fixation. The clamp assembly includes  
7     inferior and superior clamp halves that are slideably  
8     interconnected. The clamp halves are engageable about the  
9     longitudinal rods. Asher et al. (U.S. Patent No. 5,084,049) teach  
10    a pair of corrective devices for securement to a spinal column.  
11    Each corrective device includes a spine plate having a plurality of  
12    openings for receiving a fastener to connect the spine plate to a  
13    vertebra. Tsou (U.S. Patent No. 5,122,131) teaches an orthopedic  
14    device for secure mechanical coupling to an elongated surgical rod.  
15    Dubousset (U.S. Patent No. 5,147,360) teaches an osteosynthesis  
16    device for correction of spinal curvature wherein anterior and  
17    posterior rods are affixed to the vertebral bodies to apply the  
18    necessary corrective forces to the spinal column. Cotrel (U.S.  
19    Patent No. 5,154,719) teaches an implant for osteosynthesis, the  
20    implant being in the form of a screw having a rod-receiving head.  
21    Mathews (U.S. Patent No. 5,171,279) teaches a percutaneous fusion  
22    technique using suprafascial internal fixation. Schl pfer (U.S.  
23    Patent No. 5,190,543) teaches a pedicle screw having a slotted head  
24    for receiving a support rod. Mehdian (U.S. Patent No. 5,217,497)  
25    teaches an implant for fixing one segment of a spinal column to  
26    another segment, the implant being in the form of a screw having a

1 slotted head to which a support rod is anchored. Krag et al. (U.S.  
2 Patent No. 5,219,349) teaches a device for use in the controlled  
3 alignment of a fractured spine in conjunction with the Vermont  
4 Spinal Fixator. Ashman (U.S. Patent No. 5,242,445) teaches an  
5 eyebolt having two shell-like portions for engagement to a spinal  
6 rod. Vignaud et al. (U.S. Patent No. 5,261,907) teach an  
7 interconnecting device able to lock two spinal osteosynthesis  
8 fasteners. Wagner (U.S. Patent No. 5,334,203) teaches a medical  
9 construct using surgical rods and connectors. The connector  
10 includes a plate with a pair of double hook bolts to secure the  
11 plate to the surgical rods. Yuan et al. (U. S. Patent No.  
12 5,352,225) teach a dual-tier spinal clamp locking and retrieving  
13 system. Jeanson et al. (U.S. Patent No. 5,360,429) teach a device  
14 for straightening, fixing, compressing, and elongating the cervical  
15 spine. Lahille et al. (U.S. Patent No. 5,380,325) teaches a  
16 consolidated rod and plural members such as pedicular screws and  
17 vertebral claws. Acromed Corp. (European Patent Application  
18 Publication Number 0 553 424 A1) teaches a plurality of screw-like  
19 fasteners mounted to individual vertebrae and interconnected by a  
20 longitudinal rod.

21 The most common rationale for using such devices is to reduce  
22 the incidence of pseudarthrosis after bone grafting. Another  
23 rationale (typically for trauma management) is to maintain  
24 intervertebral alignment to protect the neural elements until  
25 healing occurs. Yet another rationale is to provide fixation for

1 correction of severe anomalous spine curvature due to severe  
2 scoliosis or other deformity which threatens life or health.

3 One of the early fixation methods involved the placement of  
4 screws obliquely across each facet joint involved in the grafting.  
5 However, the pseudarthrosis rate for this procedure was  
6 unacceptably high. Numerous other types of devices that variously  
7 include plates, wires, rods, bolts, hooks, and screws have evolved  
8 since that time and have resulted in a plethora of devices and  
9 instrumentation apparatus for use by the orthopedic surgeon to  
10 accomplish spinal fixation. Some of these fixation apparatus and  
11 methods require multiple adjustments to the longitudinal rods in  
12 order to adapt to specific anatomy. Although not provided by all  
13 these devices, the ideal spinal fixation apparatus would provide  
14 internal alignment and fixation not just in any one of various  
15 planes of movement, but in a full, three-dimensional construct  
16 where subject fixation apparatus is simplified, low profile, and  
17 easily manipulated and adjusted by the surgeon to allow for anatomy  
18 variations, while at the same time providing an extremely rigid  
19 construct upon tightening of connection points.

20 As shown herein before, numerous patents have been issued for  
21 various types of spine fixation devices. These devices employ  
22 different mechanical apparatus for enabling the surgeon to  
23 selectively adjust the alignment of the patient's spine and then to  
24 secure that alignment with the spine fixation device. Most of  
25 these devices are relatively difficult to adjust and require undue  
26 surgical time in their implantation. Further, due to the wide

1 variation in spinal dimensions and availability of suitable  
2 attachment sites, most devices have limited application. Further  
3 still, these devices do not allow the surgeon to easily manipulate  
4 and position the bone screws prior to final tightening of the  
5 device.

6 Another characteristic inherent in prior art spinal fixation  
7 apparatus are the manipulation restrictions due to screw thread  
8 configuration. Generally, prior bone screw thread configurations  
9 have been either single thread pitch (number of threads per unit of  
10 length) over the entire length of the bone screw, which requires  
11 that the clamping device be engaged from the beginning of the  
12 threading process, or other complex configurations involving set  
13 screws, or other devices which are either cumbersome to adjust and  
14 tighten or cause undue disruption of the cancellous bone tissue.  
15 Bone screws of differing thread pitch have an advantage that final  
16 positioning is not required until just prior to final tightening of  
17 the device, but still have the disadvantage of, due to the  
18 discrepancy in the thread pitch, causing the bone screw to create  
19 undue coaxial pressure on the lattice-like cancellous tissue of the  
20 bone, thereby increasing possible shearing or undue disruption of  
21 bone tissue.

22 A further characteristic of prior bone screw configurations is  
23 that the thread angle of the top surface of the thread is not  
24 orthogonal relative to the axis of the screw, thereby lessening  
25 gripping strength. Specifically, increasing the angle of the  
26 thread surface proximal to the bone screw head such that the angle



1 is nearly orthogonal relative to the bone screw axis,  
2 correspondingly decreases the lateral forces imposed by that thread  
3 on bone tissue by the tightening process.

4 In view of the foregoing, it would be a significant  
5 advancement in the art to provide a spinal fixation apparatus and  
6 method that was highly interchangeable, simplified, and would  
7 increase the ease of installation and adjustment while decreasing  
8 the total time required for surgical implantation and fixation. It  
9 would also be an advancement in the art to provide a spinal  
10 fixation apparatus and method that would utilize a multi-diameter  
11 threaded bone screw of the same thread pitch for all diameters,  
12 such that, upon tightening, would have no net increase in axial  
13 pressure on the cancellous bone tissue due to thread pitch  
14 variance. An even further advancement in the art would be to  
15 provide a bone screw with a modified thread configuration such that  
16 the top surface of the thread is nearly orthogonal to the axis of  
17 the bone screw, thereby decreasing the lateral pressure on the  
18 cancellous bone tissue, subsequently lessening the likelihood of  
19 shearing upon tightening. Such a novel spinal fixation apparatus  
20 and method is disclosed and claimed herein.

#### 21 22 Brief Summary and Objects of the Invention

23 This invention relates to a novel spinal fixation apparatus  
24 and method and includes specially designed C-clamps, cross-link  
25 plates, stem clamps, bone screws, and longitudinal rods--all of  
26 which are used for spinal fixation. The various components are

1 designed to be interchangeable, highly adaptable, and easily  
2 manipulated by the surgeon at time of implantation. The bone  
3 screws provide greater gripping strength and ease of implantation.

4 It is, therefore, a primary object of this invention to  
5 provide improvements in spinal fixation apparatus.

6 Another object of this invention is to provide improvements in  
7 the method for fixation of a spine for fusion.

8 Another object of this invention is to provide a spinal  
9 fixation apparatus that has interchangeable components, is greatly  
10 simplified, and has infinite capability to locate bone screws in  
11 any orientation without the necessity of bending the longitudinal  
12 rods thereby also allowing the use of more biocompatible materials,  
13 such as titanium, which exhibits less image interference (scatter)  
14 on a CT scan.

15 Another object of this invention is to provide bone screws and  
16 C-clamps that can be used on either the left or right side of the  
17 longitudinal rod, as well as directly on the longitudinal rod when  
18 situation dictates.

19 Another object of this invention is to provide a cross-link  
20 plate with a squared cross-section at its midriff to allow the  
21 cross-link plate to be bent or twisted to adapt to specific anatomy  
22 and increase ease and accuracy of implantation.

23 Another object of this invention is to provide a C-clamp which  
24 possesses two opposing indentations for secure accommodation of a  
25 manipulation tool during implantation and tightening of the various  
26 components of the construct.

1 Another object of this invention is to provide a bone screw  
2 with first and second threaded sections of different diameters but  
3 with the same thread pitch.

4 Another object of this invention is to provide a bone screw  
5 that can be positioned prior to tightening without creating undue  
6 coaxial forces on the cancellous bone tissue.

7 Another object of this invention is to provide a bone screw  
8 thread configuration that supplies greater gripping strength due to  
9 the top surface of the thread being nearly orthogonal relative to  
10 the axis of the bone screw.

11 These and other objects and features of the present invention  
12 will become more readily apparent from the following description in  
13 which preferred and other embodiments of the invention have been  
14 set forth in conjunction with the accompanying drawing and appended  
15 claims.

16  
17 Brief Description of the Drawing

18 Figure 1 is a plan view of the spine fixation apparatus of  
19 this invention shown in the environment of a portion of the  
20 lumbosacral spine;

21 Figure 2A is an exploded perspective view of a bone screw and  
22 C-clamp;

23 Figure 2B is a cross-sectional view of the C-clamp of Figure  
24 2A taken along lines 2B-2B of Figure 2A;

25 Figure 3 is a side elevation of the bone screw of Figure 2A;

3B  
w 1 Figure 3A is a greatly enlarged, fragmentary, cross-sectional  
2 view of the threads on the bone-engaging portion of the bone screw  
3 of Figure 3;

4 Figure 4A is a perspective view of the cross-link plate;

5 Figure 4B is a cross-sectional view of the cross-link plate of  
6 Figure 4A taken along lines 4B-4B of Figure 4A;

7 Figure 5A is an exploded perspective view of a stem clamp and  
8 bolt;

9 Figure 5B is a cross-sectional view of the stem clamp of  
10 Figure 5A taken along lines 5B-5B of Figure 5A; and

11 Figure 6 is a perspective view of a bone pin for use in  
12 temporarily holding the position of the construct of this  
13 invention.

14  
15 Detailed Description of the Preferred Embodiment

16 The invention is best understood from the following  
17 description with reference to the drawing wherein like parts are  
18 designated by like numerals throughout and taken in conjunction  
19 with the appended claims.

20  
21 General Discussion

22 The underlying rationale for spinal fusion is to (a) restore  
23 the integrity of the spine or to replace missing bone stock, i.e.,  
24 fracture, tumor, infection; (b) produce an arthrodesis that will  
25 suppress undesired movement between two or more bony elements that  
26 are the source of pain; and (c) maintain correction of spinal

1 deformity or to prevent progression of deformity. In general, this  
2 arthrodesis is produced by using a bone graft that will heal and  
3 mature thereby binding the involved elements intimately.  
4 Arthrodesis requires in most instances a period of immobilization  
5 to achieve this end. Importantly, the key factor in predicting  
6 successful fusion is the amount of instability; that is, if  
7 instability is moderate and bone stock good, the proportion of easy  
8 primary fusion will increase. This goal is readily accomplished  
9 using the unique apparatus and method of this invention.

10 Since fusion is performed in the region of the unstable spinal  
11 segment that one wants immobile, the use of the internal fixation  
12 apparatus increases rigidity and gives a higher rate of fusion.  
13 This resultant increased fusion rate and decreased pseudarthrosis  
14 rate gives better results and can ease postoperative management  
15 regimens. Therefore, spinal instrumentation allows correction of  
16 deformity and rigid fixation of that correction during  
17 consolidation by fusion.

18 The unique spinal fixation apparatus and method of this  
19 invention enables the surgeon to securely immobilize the desired  
20 number of lumbar vertebrae thereby providing a stable condition for  
21 the ingrowth of bone tissue to achieve true spinal fixation.  
22 Importantly, the spinal fixation components of this invention are  
23 configured to reduce, if not eliminate, the incremental movement of  
24 micromotion between the various components. The angular  
25 orientation of the bone screw placement is designed to achieve  
26 optimal fixation between the device and the vertebrae to which it

1 is affixed. The bone screws are specifically designed pass through  
2 the C-clamp without engaging the threads of the C-clamp while  
3 tapping into the pedicle, thereby allowing the surgeon to more  
4 accurately position and adjust the apparatus prior to tightening.  
5 The pedicle screw is anchored securely through pedicle into the  
6 vertebral body and simultaneously secures the C-clamp to engage the  
7 side arm portion of the stem clamp or the longitudinal rod in a  
8 tight, non-release fashion. This invention also provides the  
9 surgeon with greater ease of implantation of the fixation apparatus  
10 thereby decreasing the operative trauma and the postoperative  
11 convalescence.

12 My innovative spinal fixation apparatus centers around at  
13 least one longitudinal rod to which a plurality of bone screw and  
14 C-clamp combinations and stem clamps are attached. More than one  
15 longitudinal rod can be employed in assembling the construct of my  
16 invention and in such circumstances cross-link plates are provided  
17 to lend structural support between the two longitudinal rods. The  
18 C-clamp is configured to be slideably mounted to the longitudinal  
19 rod and securely anchored thereto by being clamped together upon  
20 threaded engagement by the bone screw. The bone screw is  
21 configured with a first, distal set of threads having a first,  
22 smaller diameter and a second, proximal set of threads having a  
23 second, larger diameter. The thread pitch for the first set of  
24 threads is identical to the second set of threads. The C-clamp has  
25 a lower jaw having threads therein which correspond to the second  
26 set of threads on the bone screw. This feature allows the bone

1 screw to be passed through the C-clamp and into threaded engagement  
2 with the underlying bone without engaging the C-clamp. However,  
3 once the bone screw has been suitably engaged into the bone the  
4 surgeon is then able to securely engage the C-clamp with the bone  
5 screw thereby securely engaging the C-clamp to either the  
6 longitudinal rod or the side arm of the stem clamp while tightly  
7 affixing the same to the bone. The identical thread pitch on both  
8 sets of threads of the bone screw means that as the bone screw  
9 engages and tightens the C-clamp, the continued axial movement of  
10 the bone screw into the bone is at the identical rate as prior to  
11 engagement of the C-clamp. This means that there is negligible  
12 change in the axial distance travelled by the bone screw during  
13 each rotation of the bone screw thereby effectively eliminating the  
14 gouging or disruption of the adjacent bone structure that would  
15 otherwise occur if one were using a prior art bone screw having a  
16 first thread pitch for the bone portion of the bone screw and a  
17 second thread pitch for engagement with the C-clamp. The end  
18 result is that my innovative bone screw not only secures the C-  
19 clamp securely against the longitudinal rod or the side arm of the  
20 stem clamp but it also is simultaneously seated more snugly into  
21 the underlying bone thereby significantly reducing the possibility  
22 of micromotion between the bone screw and the bone. This in turn  
23 significantly reduces postoperative pain and speeds healing.

24       Importantly, the overall dimensional profile of the construct  
25 created from my innovative bone screw, C-clamp, stem clamp, and  
26 longitudinal rod combination is lower or, more specifically,

1 implantable closer to the spine where it is thereby able to more  
2 securely hold the spine in the orientation determined by the  
3 surgeon. Further, the low profile means that there is a  
4 significant reduction in the moment arm as represented by the  
5 distance between the bone of the spine and the longitudinal rod.  
6 Reducing this moment arm significantly lowers the bending forces  
7 imposed on the bone by the forces resisted by the longitudinal  
8 rods.

9 Another important feature provided by the various components  
10 of the construct of my invention is that the surgeon is provided  
11 with an infinite selection of angles by which the bone screw can be  
12 directed into the bone. This feature is particularly advantageous  
13 in that the pedicle orientation varies from patient to patient and  
14 even between the different vertebra on the same spine. Angular  
15 selection for the direction of insertion of the bone screw is  
16 provided by the fact that the stem clamp is rotatable a full 360°  
17 about the longitudinal rod while the C-clamp is likewise rotatable  
18 a full 360° about either the stem or side arm of the stem clamp or  
19 the longitudinal rod. Accordingly, the surgeon is able to  
20 selectively rotate both the stem clamp and the C-clamp to thereby  
21 achieve the preselected angular orientation of the bone screw into  
22 the underlying bone structure.

23 In addition to the foregoing features of my invention, I also  
24 provide a bone pin system for temporarily securing the spinal  
25 fixation apparatus in position on the spine to permit me to analyze  
26 the construct and its spinal placement through the use of X-ray



1 analysis. Once X-ray analysis has shown that all of the elements  
2 of the construct are properly positioned it is a simple procedure  
3 to merely replace each bone pin with a bone screw.

4 Possibly the most important feature of the innovative spinal  
5 fixation apparatus of my invention is that the entire construct can  
6 be mounted to the spinal column with the bone screws properly  
7 placed prior to the final tightening of the various C-clamps and  
8 stem clamps. This final tightening procedure is readily  
9 accomplished in the absence of unacceptably altering the final  
10 orientation of the construct and without imposing distortional  
11 stresses on the construct.

#### 12 13 Detailed Description

14 Referring now to Figure 1, the unique spinal fixation  
15 apparatus of this invention is shown generally as construct 10  
16 mounted to the lumbar region of a spine 90. Spine 90 includes a  
17 sacrum 92 and a plurality of vertebra 94a-94d. Vertebra 94a-94d  
18 each include an upwardly extending spinous process 96 along with a  
19 transverse process 98 extending outwardly on each side, only one  
20 spinous process and transverse process being numbered herein for  
21 sake of simplicity in presenting this invention. A pair of  
22 longitudinal rods 12 and 14 are aligned on each side of spinous  
23 process 96 to provide longitudinal support to spine 90.  
24 Longitudinal rods 12 and 14 are shown here as being the same  
25 diameter, though differing diameter longitudinal rods could be  
26 accommodated in the assembly of construct 10 if determined to be

1 advantageous by the surgeon (not shown). The most likely  
2 configuration selected would be to utilize longitudinal rods 12 and  
3 14 of the same diameter to facilitate interchangeability between  
4 components. Longitudinal rods 12 and 14 are shown with a right  
5 angle bend to illustrate a unique feature of this invention that  
6 simplifies construct 10 as will be discussed more fully  
7 hereinafter. This orthogonal bend in longitudinal rods 12 and 14  
8 creates side arms 13 and 15, respectively, which provide an anchor  
9 point for anchoring that end of longitudinal rods 12 and 14 to  
10 spine 90.

11 Construct 10 is assembled from two lengths of stem clamps,  
12 stem clamps 30a-30b and stem clamps 70a-70d, in combination with  
13 cross-link plates 20a and 20b, C-clamps 60a-60h, and bone screws  
14 50a-50h, all of which will be discussed more fully hereinafter.  
15 Stem clamps 30a and 30b are each affixed to the respective lower  
16 end of longitudinal rods 12 and 14 and provide the mechanical  
17 structure for enabling C-clamps 60a and 60h along with their  
18 respective bone screws, bone screws 50a and 50h to secure these  
19 elements to the sacrum 92. Correspondingly, stem clamps 70a-70d in  
20 combination with C-clamps 60b-60g and bone screws 50b-50g,  
21 respectively, provide the necessary securement of longitudinal rods  
22 12 and 14 to vertebra 94a-94c, respectively. Cross-link plates 20a  
23 and 20b provide the necessary bridging mechanism between  
24 longitudinal rods 12 and 14 by being clamped thereto by stem clamps  
25 70a-70d, respectively, when stem clamps 70a-70d are secured to  
26 longitudinal rods 12 and 14, respectively. Stem clamps 30a-30b and

1 stem clamps 70a-70d are identical with the exception of length of  
2 the respective side arm and could thereby accommodate an additional  
3 cross-link plate 20 should the situation dictate.

4 It is important to emphasize at this juncture that the  
5 versatility of construct 10 is significantly enhanced by the fact  
6 that bone screws 50a-50h are capable of being directed in any  
7 preselected angular orientation into the particular underlying bone  
8 structure of spine 90. For example, the proper angular orientation  
9 of bone screws 50d and 50e is achieved by rotating the respective  
10 longitudinal rod 12 and 14 to bring side arm 13 and 15 into the  
11 desired placement relative to spine 90. Correspondingly, C-clamps  
12 60d and 60e are rotated about side arms 13 and 15 respectively, to  
13 correctly orient the angular position of bone screws 50d and 50e,  
14 respectively, with spine 90. Similarly, C-clamps 60a-60c and 60f-  
15 60h are rotatable a full 360° about the respective stems of stem  
16 clamps 30a, 30b, and 70a-70d while stem clamps 30a, 30b, and 70a-  
17 70d are also rotatable a full 360° about longitudinal rods 12 and  
18 14, respectively. This feature allows the surgeon to have an  
19 infinite choice for the angular orientation of the respective bone  
20 screws, bone screws 50a-50c and 50e-50g.

21 Referring now to Figures 2A, 2B and 3, C-clamp 60 is shown  
22 herein in combination with bone screw 50. C-clamp 60 includes a  
23 clamp body 62 having an upper jaw 61 and a lower jaw 63  
24 interconnected by a cylindrical sidewall 65. Cylindrical sidewall  
25 65 defines a lateral throughbore 64 through clamp body 62. Lateral  
26 throughbore 64 is configured to slidably receive stem 74 (Figures

1 5A and 5B) or side arms 13 and 15 of longitudinal rods 12 and 14  
2 (Figure 1), respectively. C-clamp 60 includes a transverse  
3 throughbore 66, through upper jaw 61 and lower jaw 63. The bottom  
4 portion of transverse throughbore 66 in lower jaw 63 is configured  
5 with threads 67 to engage large diameter threads 54 of bone screw  
6 50. Two opposing indentations 68a and 68b are configured for  
7 secure accommodation of a manipulation tool (not shown) by the  
8 surgeon during manipulation and tightening of C-clamp 60.

9 Bone screw 50 is configured with a bolt head 56, an enlarged  
10 neck 54, a collar 49 and shaft 52 extending downwardly therefrom.  
11 Neck 54 is threaded with threads 55 while shaft 52 is threaded with  
12 threads 53. Collar 49 is characterized by the absence of threads  
13 and has an outer circumference that approximates the outer  
14 circumference of threads 53. Bone screw 50 terminates downwardly  
15 in a blunt tip 51 at its distal end. Transverse throughbore 66 of  
16 C-clamp 60 is sufficiently large to allow the smaller diameter of  
17 threads 53 and collar 49 to pass freely through transverse  
18 throughbore 66 and, particularly, threads 67 of lower jaw 63 in a  
19 nonbinding relationship. I have found that the smooth profile of  
20 collar 49 is particularly useful in that it minimizes any tendency  
21 for threads 53 to bind with threads 67 during the final stages of  
22 mounting bone screw 50 into C-clamp 60. This tendency toward  
23 thread binding occurs due to slight angular offsets that may occur  
24 upon the final assembly of bone screw 50 into C-clamp 60. Collar  
25 49 thereby provides a smooth surface against which threads 67 can  
26 not bind.

1       The larger diameter threads 55 on neck 54 also pass through  
2       the portion of transverse throughbore 66 in upper jaw 61 freely in  
3       a nonbinding relationship until engaging threads 67 in lower jaw  
4       63.   The diameter and pitch of threads 55 are configured to  
5       threadedly engage threads 67 to bring bolt head 56 into abutment  
6       against upper jaw 61.   Further tightening of bone screw 50 will  
7       simultaneously engage bone tissue (not shown) while forcing the  
8       closing of upper jaw 61 downwardly against lower jaw 63.  
9       Accordingly, side arm 74 or longitudinal rods 12 or 14 residing in  
10      lateral throughbore 64 will be securely engaged by this clamping  
11      action of C-clamp 60.   Importantly, the thread pitch is identical  
12      for all of threads 53, 55, and 67.

13       The multiple diameter configuration of bone screw 50 as to  
14      neck 54 and shaft 52 increases flexibility in installation and  
15      adjustment while decreasing the total time required for surgical  
16      implantation and fixation by allowing the surgeon to partially  
17      position bone screw 50 in the pedicle of the vertebra 94 or sacrum  
18      92 (Figure 1), creating multiple elements of construct 10, then  
19      returning to each bone screw 50 or side arm clamps 30 and 70  
20      (Figure 1) for final adjustment and consolidation in a tight, non-  
21      release fashion.   The match of thread pitch of both smaller  
22      diameter threads 53 on shaft 52 and the larger diameter threads 55  
23      on neck 54 accommodates the tightening of the bone screw 50 into C-  
24      clamp 60 as well as the underlying bone structure without changing  
25      the axial pressure on the lattice-like cancellous bone tissue that

1 would otherwise occur if there were a thread pitch variance as in  
2 prior art devices.

3 Bone screw 50 includes a unique thread configuration of the  
4 top surface of thread 53 in that it is undercut or nearly  
5 orthogonal to axis 57 of bone screw 50 as shown by angle 59. The  
6 bottom surface of thread 53 resides at an acute angle 58. This  
7 latter angle more nearly approximates the angular surfaces of  
8 threads 55. During the tightening of bone screw 50 into the  
9 pedicle bone and subsequent clamping with C-clamp 60, the top  
10 surface of thread angle 59 serves to decrease the lateral pressure  
11 on the cancellous bone tissue in which bone screw 50 is implanted,  
12 thereby increasing the gripping capability while decreasing  
13 likelihood of disruption of cancellous bone tissue. In essence,  
14 this top surface acts to undercut and thereby more securely embed  
15 threads 53 into the bone structure.

16 With specific reference to Figure 2B, C-clamp 60 is shown with  
17 an angular offset 69 in the relationship between upper jaw 61 and  
18 lower jaw 63. Angular offset 69 is in the range of one to ten  
19 degrees and allows bolt head 56 to strike the elevated edge of  
20 upper jaw 61 first and then as threads 55 on neck 54 continue to  
21 tightly engage threads 67 in lower jaw 63 cause upper jaw 61 to be  
22 pressed downwardly into a parallel orientation with lower jaw 63.  
23 This latter configuration allows the bottom face of bolt head 56 to  
24 rest uniformly against the top face of upper jaw 61 for a more  
25 secure engagement between bolt head 56 and upper jaw 61.  
26 Accordingly, angular offset 69 is designed to accommodate the

1 necessary closure motion between upper jaw 61 and lower jaw 63 in  
2 order to securely clamp either stem 74 or longitudinal rod side  
3 arms 13 and 15 within the confines of lateral throughbore 64 while  
4 simultaneously providing a full 360° contact surface for bolt head  
5 56 against upper jaw 61.

6 Referring now to Figures 4A and 4B, cross-link plate 20 is  
7 shown more clearly and includes a shank 22 having an eyelet 24 at  
8 one end and an eyelet 25 at the other end. Shank 22 is formed with  
9 a waist-like configuration having a square profile 23 as shown in  
10 the cross-sectional view of Figure 4B. The squared, cross-section  
11 at profile 23 of shank 24 allows the cross-link plate 20 to be  
12 deformably shaped into an upwardly convex curvature or otherwise  
13 twisted or bent, to accommodate specific anatomical features  
14 encountered during implantation thereby increasing the ease and  
15 accuracy of implantation and fixation of construct 10 to spine 90.  
16 This feature further allows the surgeon to place longitudinal rods  
17 12 and 14 closer to spine 90 since cross-link plate 20 can be  
18 deformably configured to achieve this placement. In addition to  
19 other adjustments, elongation of slots 25 and 27 in eyelets 24 and  
20 25, respectively, provides the surgeon with a greater degree of  
21 axial adjustability in securing cross-link plate 20 between  
22 longitudinal rods 12 and 14. Further, cross-link plate 20 can be  
23 mounted at each stem clamp, stem clamps 30 and 70, located along  
24 the length of construct 10.

25 Referring now to Figures 5A and 5B, stem clamp 70 is shown  
26 with bolt 80. Stem clamp 30 (Figure 1) is essentially identical to

1 stem clamp 70 the only difference being the relative length of the  
2 respective stems 34 and 74. Stem clamp 70 includes a clamp body 72  
3 having a generally C-shaped configuration with an upper jaw 71 and  
4 a lower jaw 73. Lower jaw 73 is angularly offset from upper jaw 71  
5 by an angle between one and ten degrees as shown by angle 79.  
6 Upper jaw 71 is connected to lower jaw 73 through a cylindrical  
7 sidewall 75 having a lateral throughbore 78 therethrough. Lateral  
8 throughbore 78 slidably receives and ultimately engages  
9 longitudinal rod 12 or 14 as will be discussed hereafter.  
10 Importantly, cylindrical sidewall 75 is provided with a limited  
11 degree of resiliency between upper jaw 71 and lower jaw 73 so that  
12 when these jaws are urged together the subject clamping action of  
13 longitudinal rod 12 or 14 in lateral throughbore 78 can occur.  
14 Clamp body 72 includes a transverse bore 76 through upper jaw 71  
15 and lower jaw 73. The portion of transverse bore 76 through upper  
16 jaw 71 is unthreaded so that bolt 80 can be passed through upper  
17 jaw 71 freely in a nonbinding relationship to threadedly engage  
18 threads 77 (Figure 4B) in lower jaw 73. Specifically, bolt 80 is  
19 configured with a shaft 82 having a bolt head 88, a neck 56 and  
20 threads 84. Threads 84 are configured to threadedly engage threads  
21 77 to bring bolt head 88 into abutment against upper jaw 71.  
22 Further tightening of bolt 80 in stem clamp 70 forces the closing  
23 together of upper jaw 71 toward lower jaw 73 to eliminate angle 79  
24 so that longitudinal rod 12 or 14 residing in lateral throughbore  
25 78 will be securely engaged by this clamping action. Accordingly,  
26 stem clamp 70 is similar to C-clamp 60 in that it is also



1 configured with an angular offset similar to angular offset 69  
2 (Figure 2B) for the same purpose.

3 Referring now to Figure 6, the bone pin for use in temporarily  
4 mounting construct 10 to spine 90 is shown at 100 and includes a  
5 shaft 102 having a diametrically enlarged portion which serves as a  
6 handle 106 and a diametrically reduced portion which serves as a pin  
7 104. Pin 104 terminates distally in a blunt tip 105. Bone pin 100  
8 is specifically designed to be positioned temporarily in transverse  
9 throughbore 66 of C-clamp 60 (Figure 2A) with pin 94 extending  
10 downwardly into the hole (not shown) reamed into spine 90, the hole  
11 in spine 90 being intended for the threaded engagement therewith by  
12 bone screw 50 (Figure 3). This feature allows the surgeon to use  
13 a plurality of bone pins 100 to temporarily secure construct 10 to  
14 spine 90 and then suitably analyze all features of construct 10 in  
15 its relationship to spine 90 by using conventional X-ray analysis  
16 techniques. This unique feature of my invention significantly  
17 improves the fixation of spine 90 reducing the misalignment of any  
18 of the elements of construct 10 relative to spine 90. Further,  
19 bone pin 100 provides a simple technique for enabling the surgeon  
20 to quickly and accurately determine the correct placement of bone  
21 pin 100 prior to insertion of bone screw 50 into the underlying  
22 bone structure of spine 90.

## The Method

Construct 10 is affixed to spine 90 by a very straightforward procedure. Specifically, all of the holes to receive bone screws 50a-50h are sited and then selectively reamed. Thereafter, longitudinal rod 12 having the predetermined length and diameter is selected. Stem clamp 30b is attached to the end thereof and C-clamp 60h is mounted to stem 74 (Figures 5A and 5B). Bone screw 50h is then embedded in sacrum 92 to loosely hold stem clamp 30b and longitudinal rod 12 to sacrum 92. During this procedure, longitudinal rod 12 is oriented upwardly out of the surgical incision (not shown). The surgeon has previously slipped the preselected number of stem clamps 70 on longitudinal rod 12. Bone pin 100 is then passed through C-clamp 60e and inserted in the pedicle within vertebra 94c to loosely hold C-clamp 60e to spine 90. Longitudinal rod 12 is then slidingly adjusted to pass through throughbore 64 of C-clamp 60e. In this manner, longitudinal rod 12 is oriented relative to spine 90. The next step is for the intervening stem clamps 70c and 70d to be mounted to spine 90 using C-clamps 60f and 60g in combination with a plurality of bone pins 100. Longitudinal rod 14 is also positioned on spine 90 following the identical procedure used for longitudinal rod 12.

With most of the elements of construct 10 held in place on spine 90 through the use of a plurality of bone pins 100 the surgeon is able to use X-ray techniques to accurately determine the correct placement of construct 10 as well as bone screws 50. This is particularly advantageous since bone screws 50 have yet to be

1 mounted to spine 90. Once it has been determined that all elements  
2 of construct 10 are suitably positioned on spine 90 the surgeon is  
3 readily able to secure construct 10 to spine 90 in this  
4 predetermined position by simply removing and replacing one by one  
5 each of bone pin 100 with a bone screw 50. Thereafter, cross-link  
6 plates 20 are mounted to stem clamps 30 and 70 and final securement  
7 thereof is accomplished by tightening bolt 80 therein.  
8 Importantly, cross-link plates 20a and 20b are suitably shaped as  
9 described hereinbefore and then mounted between the respective  
10 pairs of stem clamps 70a-70d by having bolts 80 (Figure 4A) secured  
11 to stem clamps 70a-70d. If further stabilization is required, an  
12 additional cross-plate 20 could be installed between stem clamp 30a  
13 and stem clamp 30b.

14 With each of bone screws 50a-50d in place along with stem  
15 clamps 30a and 30b and stem clamps 70a-70d, the surgeon is now  
16 ready to make any final adjustment to construct 10 and then  
17 suitably tighten all of these elements as needed to achieve the  
18 desired fixation of spine 90 with the spinal fixation apparatus of  
19 construct 10 without imposing undesirable forces on spine 90.  
20 Specifically, if one has ever attempted to achieve final tightening  
21 of two moveable elements through the use of a set screw system, one  
22 has experienced the fact that the act of tightening almost always  
23 results in a rotational movement being imparted by the set screw  
24 against the element being engaged by the set screw. To compensate  
25 for this notorious characteristic of a set screw, it is customary  
26 for the operator to adjust the orientation of the movable element

1 so that when the set screw has been suitably tightened (and has  
2 thereby rotated the element to, hopefully, its final position) the  
3 element will be set at its desired position. Precise final  
4 alignment of the two elements using the prior art set screw system  
5 is, therefore, a matter of experience coupled with extensive trial  
6 and error. However, with respect to the spinal support system  
7 provided by construct 10 presented herein, such a final fixation  
8 system for the various components of construct 10 is unnecessary.  
9 In particular, it is poor medical practice to implant a spinal  
10 fixation device in a patient in such a way as to impose  
11 unacceptable forces on the spine as a result of the final position  
12 setting of the components in the spinal fixation device. Construct  
13 10 eliminates all of these problems by the unique design of its  
14 components. Stem clamps 30 and 70 impart absolutely no rotational  
15 forces against the particular element engaged thereby.  
16 Additionally, the clamping action of C-clamps 60 involve the  
17 constriction of the respective rod elements in the absence of any  
18 rotational forces being imposed on the rod element. As further  
19 assistance and security during tightening, two opposing  
20 indentations 68a and 68b on C-clamp 60 (Figure 2B) are configured  
21 to accommodate engagement by a manipulation tool (not shown) during  
22 adjustment and tightening.

23 Construct 10 provides numerous advantages in the art of spine  
24 fixation in that it readily allows the surgeon to adapt the final  
25 configuration to any anatomical condition encountered on spine 90.  
26 Specifically, the combination of stem clamps 30 and 90 in

1 conjunction with C-clamps 60 provides the surgeon with unlimited  
2 ability to direct the placement of bone screw 50 at any angle in  
3 both the sagittal plane and the coronal plane. Further, stems 34  
4 and 74 permit significant translational placement of bone screw 50.  
5 These features are very advantageous since the entry angle as well  
6 as the entry point for bone screw 50 will vary from position to  
7 position on spine 90. The end result is that I have effectively  
8 eliminated the need to bend or shape longitudinal rods 12 and 14.  
9 The only bending or contouring required during the surgical  
10 procedure is that of cross-link plate 20. This shaping is easily  
11 accomplished by clasping each of eyelets 24 and 25 in the jaw of a  
12 suitable tool and applying the necessary bending/twisting forces on  
13 shank 22.

14 In summary, construct 10 provides a distinct advantage to the  
15 surgeon (not shown) in that it allows the surgeon to create any  
16 suitable spatial relationship between construct 10 and spine 90 for  
17 the purpose of packing bone graft (not shown) therebetween while at  
18 the same time providing a very strong, rigid, spinal support  
19 system. This advantage is possible through the use of the  
20 innovative clamping system involved in stem clamps 30 and 70. Not  
21 only do these clamping devices provide a very solid linkage between  
22 components in construct 10, but they also provide a highly  
23 advantageous degree of assembly flexibility in assembling construct  
24 10. Specifically, bone screws 50a-50h are almost never secured to  
25 spine 90 in a direction that is perpendicular to a plane  
26 represented by the axis of longitudinal rod 12 and side arm 13, for

1 example. The ideal placement of bone screws 50a-50h is almost  
2 always at some angular offset so that the various components of  
3 construct 10 are particularly useful in that they accommodate the  
4 precise placement of bone screws 50a-50h regardless of the  
5 respective angular orientation. Further, once in place, the entire  
6 spinal support apparatus of construct 10 is then securely affixed  
7 in the final configuration to thereby provide a rigid spinal  
8 support system for spine 90. This latter feature is important and  
9 is made possible by the various elements that constitute construct  
10 10.

11 The present invention may be embodied in other specific forms  
12 without departing from its spirit or essential characteristics.  
13 The described embodiments are to be considered in all respects only  
14 as illustrative and not restrictive. The scope of the invention  
15 is, therefore, indicated by the appended claims rather than by the  
16 foregoing description. All changes which come within the meaning  
17 and range of equivalency of the claims are to be embraced within  
18 their scope.

19 What is claimed and desired to be secured by United States  
20 Letters Patent is: